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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,566	03/08/2004	Clark R. Baker JR.	TYHC:0069/FLE (P0426R)	1089

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EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,566	BAKER, CLARK R.	
	Examiner	Art Unit	
	KAREN E. TOTH	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims call for evaluating the reliability of the calculated results by applying metrics to a method of calculation; the present specification calls for using signal quality metrics to determine the reliability of a result. Further, it's not clear how applying metrics to a method as required by the claim limitations could be useful, since the method will not change. For the purposes of examination, the claims will be treated as though they read "reliability of the first heart rate using metrics applied to the first signal". Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. Claims 1, 3-5, 7-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker (US Patent Application Publication 2002/0137994) in view of Harada (US Patent 5759157).

Regarding claim 1, Baker discloses a method of determining a heart rate from a pulse oximetry signal comprising determining first and second heart rates from a pulse oximetry signal using first and second methods (paragraphs [0056]-[0057]), and using metrics to determine which heart rate to use (paragraphs [0034], [0057], [0177]). Baker does not disclose applying the metrics to only the first heart rate, and using the first rate if the metrics indicate that it is reliable and using the second when the metrics indicate that the first heart rate is unreliable. Harada teaches a method of analyzing biosignals comprising evaluating the reliability of a first calculated result, and, based on that reliability determination, deciding whether to use the first calculated result or a second one (column 3, lines 44-48; column 5, lines 17-20), in order to minimize the number of required processing steps. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed the method of Baker and applied confidence metrics to only one of the signals, as taught by Harada, in order to minimize the amount of signal processing.

Regarding claim 3, Baker further discloses using pulse oximetry to obtain heart rate signals where, as part of determining the most accurate heart rate signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]).

Regarding claim 4, Baker further discloses using pulse oximetry to obtain heart rate signals, where the signals are used to determine a pulse period (average period of the pleth), which is converted into a heart rate (pulse rate) (paragraph [0057]).

Regarding claim 5, Baker discloses a system comprising a first heart rate calculator that determines a heart rate from a pulse oximetry signal using a first method (paragraph [0056]), a second heart rate calculator that determines a heart rate from the pulse oximetry signal using a second method (paragraph [0057]), and an evaluator configured to evaluate the reliability of the signals using metrics and a selector that chooses a heart rate based on the reliability results (paragraphs [0057], 0177]). Baker does not disclose the evaluator applying the metrics to only the first rate, and using the first rate if it is reliable and using the secod rate if the first is unreliable. Harada teaches a system for analyzing biosignals comprising an evaluator for determining the reliability of a first calculated result, and, based on that reliability determination, using a selector to decide whether to use the first calculated result or a second one (column 3, lines 44-48; column 5, lines 17-20), in order to minimize the number of required processing steps. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Baker and applied confidence metrics to only one of the signals, as taught by Harada, in order to minimize the amount of signal processing.

Regarding claim 7, Baker further discloses using pulse oximetry to obtain heart rate signals where, as part of determining the most accurate heart rate signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]).

Regarding claims 8 and 10, Baker discloses a pulse oximetry system comprising a sensor adapted to provide a signal related to a physiological constituent (paragraphs [0035], [0052]) and

a monitor adapted to process the signal to determine a pulse period, the monitor comprising software adapted to process the signal to determine a first pulse period using a first method (paragraph [0056]), software adapted to process the signal to determine a second pulse period using a second method (paragraph [0057]), and an evaluator configured to evaluate the reliability of the signals using metrics and a selector that chooses a heart rate based on the reliability results (paragraphs [0057], 0177]). Baker does not disclose the evaluator applying the metrics to only the first rate, and using the first rate if it is reliable and using the secod rate if the first is unreliable. Harada teaches a system for analyzing biosignals comprising an evaluator for determining the reliability of a first calculated result, and, based on that reliability determination, using a selector to decide whether to use the first calculated result or a second one (column 3, lines 44-48; column 5, lines 17-20), in order to minimize the number of required processing steps. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Baker and applied confidence metrics to only one of the signals, as taught by Harada, in order to minimize the amount of signal processing.

Regarding claim 9, Baker further discloses using pulse oximetry to obtain physiological signals where, as part of determining the most accurate pulse period signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]).

Regarding claim 11, Baker discloses a method of determining a heart rate in a pulse oximeter comprising determining a first pulse period from a pulse oximetry signal using a first method (paragraph [0056]) and a second pulse period from the signal using a second method (paragraph [0057]), and using metrics to determine which pulse period is reliable and should be converted to a heart rate (paragraphs [0057], [0177]). Baker does not disclose applying the

metrics to the pulse period, and using the first rate if the metrics indicate that it is reliable and using the second when the metrics indicate that the first pulse period is unreliable. Harada teaches a method of analyzing biosignals comprising evaluating the reliability of a first calculated result, and, based on that reliability determination, deciding whether to use the first calculated result or a second one (column 3, lines 44-48; column 5, lines 17-20), in order to minimize the number of required processing steps. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed the method of Baker and applied confidence metrics to only one of the signals, as taught by Harada, in order to minimize the amount of signal processing.

Regarding claim 13, Baker further discloses using pulse oximetry to obtain physiological signals where, as part of determining the most accurate pulse period signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]).

6. Claims 2, 6, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker in view of Harada, and further in view of Leon (US Patent 5365934).

Regarding claim 2, Baker in view of Harada discloses all the elements of the current invention, as described above, except for determining that the first heart rate is unreliable after a pulse is rejected.

Leon discloses a method of using multiple heart rate signals to determine an accurate heart rate where a first rate is considered unreliable after it is rejected, in favor of an alternate heart rate candidate (column 12, lines 46-52), in order to ensure that the most accurate heart rate is obtained. It would have been obvious to one of ordinary skill in the art at the time the

invention was made to have made the method of Baker in view of Harada and considered the first heart rate to be unreliable after its rejection, as taught by Leon, in order to ensure that the most accurate heart rate is obtained.

Regarding claim 6, Baker in view of Harada discloses all the elements of the current invention, except for the selector determining that the first heart rate is unreliable when metrics indicate that a pulse is rejected.

Leon discloses using multiple heart rate signals to determine an accurate heart rate where a first rate is considered by a selector to be unreliable after it is rejected, in favor of an alternate heart rate candidate (column 12, lines 46-52), in order to ensure that the most accurate heart rate is obtained. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Baker in view of Harada and considered the first heart rate to be unreliable after its rejection, as taught by Leon, in order to ensure that the most accurate heart rate is obtained.

Regarding claim 12, Baker in view of Harada discloses all the elements of the current invention, as described above, except for determining that the first pulse period is unreliable after a pulse is rejected.

Leon discloses a method of using multiple pulse period signals to determine an accurate pulse period where a first pulse is considered unreliable after it is rejected, in favor of an alternate pulse period candidate (column 12, lines 46-52), in order to ensure that the most accurate pulse period is obtained. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Baker in view of Harada and

considered the first pulse period to be unreliable after its rejection, as taught by Leon, in order to ensure that the most accurate pulse period is obtained.

Response to Arguments

7. Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735